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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,818	05/23/2001	Daniel M. Gorman	DX01170K	8990

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EXAMINER	
JIANG, DONG	
ART UNIT	**PAPER NUMBER**
1646	12

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,818	GORMAN, DANIEL M.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7 & 9* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's election with traverse of Group III invention, represented by the original claims 7, 8 and 11, directed to SEQ ID NO:12, in Paper No. 11, filed on 26 December 2002 is acknowledged. The traversal is on the ground(s) that when an antibody to SEQ ID NO:12 is used as a therapeutic or pharmaceutical, an antigen:antibody complex of Group IV would form, and that it would not be a serious burden to examine the claims in both groups together. This argument is persuasive, and the restriction requirement between Groups III and IV is withdrawn.

Applicant's amendment in paper No. 11 is acknowledged and entered. Following the amendment, claims 1-20 are canceled, and the new claims 21-26 are added.

Currently, claims 21-26 are pending and under consideration.

Applicants submission of IDS references listed on PTO-1449, paper No. 7 and 9, is acknowledged. It is noted that the relevance of the references AE-AG of paper No. 7, and AL-AN of paper No. 9 cannot be assessed as the references are nucleic acid or amino acid sequences, and no indication of relevance or alignment to the disclosed sequences has been provided.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 21-26 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, specific, or well-established utility.

Claims 21-26 are directed to a binding composition of an antibody specific to the polypeptide of SEQ ID NO:12 or an antigenic fragment thereof, and a method of using the

composition. Said polypeptide is a putative cytokine receptor-like subunit molecule, and designated DNAX cytokine receptor subunit 9 (DCRS9).

The specification discloses a human polypeptide having an amino acid sequence of SEQ ID NO:12. As indicated in the specification, human sequences related to cytokine receptors were identified from genomic sequence database using, e.g., the BLAST server (page 69, liens 16-17), said DCRS9 polypeptide is, therefore, identified as a cytokine receptor-like subunit molecule based on its sequence homology to known cytokine receptors. As such, the specification further asserts that these receptors *should* mediate phosphotase or phosphorylase activities (page 42, lines 25-26) as they have characteristic motifs of receptors signaling through the JAK pathway (page 43, lines 29-30, and 35-37), and *may* be useful as phosphate labeling enzymes to label substrates (page 42, lines 31-32); that they may also be functional immunogens or antigens (page 42, lines 32-33); and that the cytokine receptor-like proteins will have a number of different biological activities, e.g., modulating cell proliferation or in phosphate metabolism, and such will generally result in modulation of an inflammatory function, innate immunity response, or a morphological effect (page 43, lines 23-27). Furthermore, the specification asserts that the cytokine receptors, fragments thereof, antibodies, compounds identified using the receptors or the antibodies *should* be useful in diagnosis, treatment, screening for ligand and drug development (page 65, the second and the fourth paragraphs; page 67, the second paragraph; and page 58, the second paragraph).

The asserted utilities are not considered to be substantial because the specification fails to disclose any particular function, biological significance, or any known ligand for the putative cytokine receptor DCRS9. The speculation that the disclosed polypeptides would have similar functions as other known cytokine receptor proteins based on the sequence homology cannot be accepted in the absence of supporting evidence, because generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a known protein. For example, in the transforming growth factor (TGF) family, Vukicevic et al. (1996, PNAS USA 93:9021-9026) disclose that OP-1, a member of the TGF-family of proteins, has the ability to induce metanephrogenesis, whereas closely related TGF-family members BMP-2 and TGF- 1 had no effect on metanephrogenesis under identical conditions (p. 9023, paragraph bridging

columns 1-2). Additionally, IL-18 receptor (IL-18R) was thought to be another IL-1 receptor (IL-1R) base on the sequence homology, and therefore, designated IL-1 receptor-related protein (IL-1Rrp) when it was first discovered, and its ligand was unknown (Parnet et al., J. Biol. Chem., 1996, 271(8): 3967-70). IL-1Rrp is now known as IL-18R, has a distinct ligand, and possesses distinct function from IL-1R even though it is a member of IL-1R family. In the instant case, established utilities for other known cytokine receptors, therefore, cannot be automatically applied to DCRS9 without defined biological properties. It is noted that none of the asserted utilities is DCRS9 specific. Further, even if the asserted utilities were DCRS9 specific, uses such as modulating cell proliferation or an inflammatory function, and in phosphate metabolism cannot be considered specific and substantial as no biological significance can be interpreted from such ambiguous assertion.

Therefore, each of the disclosed utilities requires additional knowledge about the ligand and/or functions of the claimed DCRS9 receptor or the antibody thereof before the antibody can be used for a specific purpose, such as those set forth in the specification. The specification does not provide any such specific information about SEQ ID NO:12 or the antibody thereof. The disclosed uses in drug development, diagnosis, and treatment are not credible, in the absence of knowledge of the ligands, which said DCRS9 binds, or any disease or condition which could be so diagnosed, or treated by the polypeptide or the antibody thereof. Therefore, there is no immediately available patentable utility for the antibody of the DCRS9. Upon further research, a specific, and substantial utility might be found for the DCRS9 or the antibody thereof. This further characterization, however, is part of the act of invention, and until it has been undertaken, the claimed invention is incomplete.

The instant situation is analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention

must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. ... a patent is not a hunting license. ... [i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to polypeptides of as yet undetermined function or biological significance. There is no evidence of record or any line of reasoning that would support a conclusion that said DCRS9 or the antibody thereof was, as of the filing date, useful for diagnosis and treatment of any disorders as indicated the specification. Until some actual and specific biological significance can be attributed to the polypeptides identified in the specification as DCRS9, or the antibody thereof, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there was no immediately apparent or "real world" utility and the claimed invention is incomplete as of the filing date.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-26 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial or credible utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 is indefinite and confusing for the recitation of "*further* comprising", which indicates an additional active ingredient. However, it seems that further limiting the active ingredient of the independent claim 21 is intended.

Claim 23 is indefinite for the recitation of "a *composition comprising* the binding *composition*" as it is confusing to have a composition comprise a composition. "The composition of claim 21, further comprising a carrier" is suggested.

Claim 24 is indefinite because a kit claim, by definition, must contain two or more elements, and the interrelationships between the elements must be explicitly stated (see In re Venezia, 530 USPQ 2d 956 (CCPA 1975)). Instructional material is not given weight as an element, therefore, the claim is an improper kit claim as it requires at a minimum only the compound and instructional material. Further, a kit usually comprises *a compartment* containing the product(s). In the instant case, it is unclear what is the interrelationship between the compartment and the binding composition.

Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the method steps of the process. It is unclear how the complex is bound to a cell.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 21-23, 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Koskinen et al. (J. Immunol., 1998, 160:4943-50).

Koskinen discloses a chicken CD5 molecule (Fig. 1), which comprises amino acid fragments having 100% sequence identity to fragments of amino acids 123-126, 318-322, 453-456 and 458-461 of SEQ ID NO:12 of the instant application (see computer printout of the search results). Further, Koskinen teaches a monoclonal antibody, 2-191, which specifically binds to the CD5 expressed on the transfected COS cells, and a method of using thereof (page 4943, under "Antibodies" in the right column; and page 4944, the second paragraph of the left column and the second paragraph of the right column). The antibody of the reference, therefore, anticipates claims 21, 22, 25 and 26 as being a binding composition, which binds to a polypeptide comprising an antigenic fragment of SEQ ID NO:12, a monoclonal antibody, forming an antigen:antibody complex bound to a cell. With respect to claim 23, although Koskinen does not explicitly mention a composition comprising the antibody and a carrier, it is well known in the art that a protein agent such as an antibody is usually used in combination with other agent(s), such as dissolving solutions, and can not be used as its crystal form alone. Dissolving solutions, such as water, buffer, or media, meet the limitation of being "a carrier". Therefore, the reference also anticipates claim 23.

Claims 21-23 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Strachan, US 6,150,502.

Strachan discloses a muring skin cell protein having an amino acid sequence of SEQ ID NO:303, which is 57.7% identical to SEQ ID NO:12 of the present invention, and comprises amino acids 1-44, 184-351, 356-421 and 423-657 of the SEQ ID NO:12 with 100% sequence identity (see computer printout of the search results). Additionally, Strachan teaches that the polypeptide may be used to raise antibodies (column 11, lines 6-8), and that antibodies to the polypeptides of the invention may be used for modulating immune responses and for treatment of diseases (column 9, lines 46-50). The reference, therefore, anticipates claims 21 and 22 as Strachan's antibody would specifically bind to the polypeptide of SEQ ID NO:12 of the instant invention because of the sequence identity between the referenced polypeptide and SEQ ID NO:12 of the instant invention, and the antibody would be at least a polyclonal antibody. The

reference also anticipates claim 23 for the reasons addressed above. With respect to claim 25, even though Strachan does not explicitly teach a method of producing an antigen:binding composition complex, the reference teaches the application of antibodies to the polypeptides for modulating immune responses and for treatment of diseases, and thus, an antigen:antibody (binding composition) complex would inherently formed in Strachan's methods. Therefore, the reference also anticipates claim 25.

Claims 22-24, 30 and 31 are rejected under 35 U.S.C. 102(a) as being anticipated by Strachan et al., WO 99/55865-A1 (provided by applicants), for the same reason above as the pertained disclosure in WO 99/55865-A1 is identical to that in US 6,150,502.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koskinen et al. (J. Immunol., 1998, 160:4943-50), or Strachan, US 6,150,502.

The teachings of Koskinen and Strachan are reviewed above. The references do not teach a kit containing said composition. However, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to make a kit containing said composition and instructions for the purpose of research and/or clinical applications, such as immunoassays, because such kit would facilitate the applications, and commercial distribution. Further, packing a composition in a kit is old and well known in the art.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
3/10/03